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16

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/913,811 09/24/97 SUGIHARA

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EXAMINER

HM12/0816

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ART-UNIT

PAPER NUMBER

17

1645

DATE MAILED:

08/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No. 08/913,811	Applicant SUGIHARA HIROKAZU
Examiner Padma Baskar	Group Art Unit 1645



Responsive to communication(s) filed on Jun 27, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

Claim(s) 1-16 is/are pending in the application.  
Of the above, claim(s) 1-11 is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 12-16 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claims \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

Notice of References Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/27/00 has been entered.
2. Claims 12-15 have been amended and new claim 16 has been added. Claims 1-11 have been withdrawn from consideration as being directed to a non-elected invention. Claims 12-16 are pending in the application.
3. The amendment filed 6/27/00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claim 12, "chronic effect", "chronic response", "electrodes coated with collagen covering" and In claim 16, "measuring sample at least 3 days after addition step.

Applicant is required to cancel the new matter in the reply to this Office action.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 12, 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is rejected as being vague and indefinite for the recitation of "chronic," and "chronic response." What are the metes and bounds of "chronic" and "chronic response"? Is it months or days? If this method is testing the effect of medicines on chronic neural or muscle tissue samples, how many times is this medicine being added to the culture? Is this medicine stable for a chronic culture? What are these chemical substances that are used as medicines?

Does electric stimulus have any effect on the neural or muscle tissue?

Claims 14 and 15 are rejected as being vague and indefinite for the recitation of "unknown concentration." If unknown concentration of medicines are added to the culture, how the effect is compared with different medicines?

Claim 16 is confusing. The recitation of "wherein the step chronic measuring after the step of adding a chemical substance to the neural or muscle tissue sample takes place at least three days after said addition step. Does applicant intend to say "The method of claim 12 for testing the chronic effect on neural or muscle tissue samples of chemical substances as medicine, wherein said chronic means at least three days after addition of medicine."

6. In view of applicants amendment to the claims, Examiner has withdrawn rejections under 35 U.S.C.102 (b) for claims 12-15.

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7. The rejection of claims 12-16 under 35 U.S.C. 103(a) as being as being unpatentable over Nisch et al (Biosense.Bioelect 1994, 9:737-741) is maintained. This rejection is maintained for essentially the same reasons as the rejections of claims 12-15 under this statutory provision, as set forth in the last Office action.

Claims are directed to medicine testing device and a method of testing the chronic effect on neural or muscle tissue samples using the said device. The device comprises a plurality of micro electrodes coated with collagen and a visible property detection system.

Nisch et al describes a method which comprises a detector for detecting electrical properties of neuronal activity in vitro (page 738-739). He measures a detectable electrical signal before and after stimulation in figure 7 which is observed (i.e visible property). He further describes a testing device comprising electrical measurement portion (i.e visible) visible detection portion (Figure 3-monitor, figure 4, figure 5, figure 6 etc).

Nisch et al does not teach that the method and device are used for tissues. However, Stedman's Medical Dictionary defines tissue as "a collection of similar cells and the intercellular substances surrounding them . There are four basic tissues in the body: 1) epithelium; 2) the connective tissue, including blood, bone, and cartilage; 3) muscle tissue; and 4) nerve tissue. In addition, while the specification puts forth preferred embodiments, the specification does not define or restrict the term tissue to a particular embodiment. Therefore , based on Stedman's Medical Dictionary the term tissue encompasses blood , which are single cells floating.

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It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the Nisch et al method and device with a reasonable expectation of success because use of this method and device for tissue culture system are readily available. An artisan of ordinary skills would have been motivated to make such a device and method for measuring the electrical properties of tissues before and after the addition of medicine or drugs because it would have helped in determining the toxicity of the drug on tissue as taught by Nisch et al.

Applicants' arguments filed on 6/27/2000, have been fully considered but they are not deemed to be persuasive. Applicant argues that Nisch et al does not suggest the use of or suitability for placement of a tissue slice and medicine on collagen coated microelectrodes in an array. Examiner disagrees with the applicant. The art teaches that the attractive technique of this device is to record extracellular electrophysiological potentials with thin film microelectrode array in to the floor of tissue chamber (see page 737, first paragraph) and further this technique can be carried out in sterile chambers (see page 737 first and second paragraphs) using large number of neurons. Furthermore, the prior art teaches (page 737, second paragraph) the device had to be biocompatable, resistant to a saline environment and sterilization and easily maintained in cell culture conditions. Therefore, one could place tissue and medicine in those chambers. To increase adhesion, electrodes are coated with Cr and then gold (i.e. collagen coated micro electrodes: new matter). Further Nisch suggests that (page 737, first paragraph) monitoring extracellular neuronal activity in vitro over extended periods of time should be helpful in answering many questions about neuronal network development and function. It would be

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obvious for a person of ordinary skill in the art at the time invention was made to use Nisch's device and method for measuring electrical properties of tissues before and after addition of medicine or drugs for a long time because Nisch teaches this device and method are useful for measuring electrical or visible properties of neurons and hence one could use this for neural or muscle tissue. The claimed invention is *prima facie* obvious in view of the prior art absent any convincing evidence to the contrary. Therefore, this rejection is maintained.

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 12-16 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 5,563,067. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims of the instant application and those of U.S. Patent No. 5,563,067 are drawn to apparatus and a method for measuring the electrical and physical characteristic of cells. While 1-13 of U.S. Patent No. 5,563,067, specifically recite an apparatus for measurement of electrical and physical characteristic of cells. It does not specifically recite measuring the properties of

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tissue with or without addition of medicines. However, it would have been obvious to one of ordinary skill in the art to substitute any tissue in the claimed methods and device in order to measure electrical and physical properties of tissue with or without addition of medicines.

10. No claims are allowed.

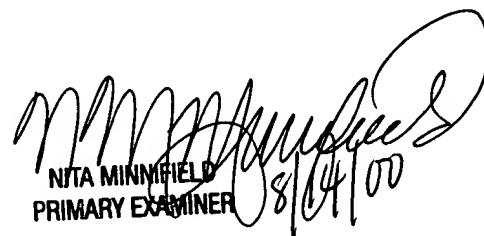
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

8/14/00

  
NITA MINNFIELD  
PRIMARY EXAMINER  
8/14/00